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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,883	10/06/2000	Bernard R. Brodeur	047998/0197	3090

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	PAPER NUMBER
1645	12

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/684,883	Brodeur
Examiner	**Art Unit**
Mark Navarro	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *91-173* is/are pending in the application.

4a) Of the above, claim(s) *91-123, 126, 131, 132, and 138-169* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *124, 125, 127-130, 133-137, and 170-173* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *3 & 4*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group V, claims 124-130, 133-137, 170-173, and SEQ ID NO: 2 in Paper No. 11, received October 16, 2002 is acknowledged. The traversal is on the ground(s) that methods of making and using the claimed product should be rejoined upon indication of allowability of the product claims (*In re Ochai*, 71 F. 3d 1565 (Fed. Cir. 1995). Applicant's further assert that once the species of SEQ ID NO: 2 has been found allowable, the Examiner will be obliged to examine the other species, namely SEQ ID Nos 4, 6, and 8. This is not found persuasive because first, no product claims have been found allowable, consequently *In re Ochai* is not applicable. Second, Applicant's appear to be under the impression that an election of species was applied for a single sequence. However, no such election of species was implied or made. As set forth in MPEP 803.04 biological molecules with different sequences are separate inventions. In view that each of the proteins identified by SEQ ID NO: 2, 4, 6, and 8 each have a separate primary, secondary, and tertiary structure, as well as being isolated from different strains, the proteins are considered to be separate inventions subject to restriction. Consequently, upon the indication of SEQ ID NO: 2 being allowable, the Examiner will not be obliged to examine the other independent and distinct molecules identified as SEQ ID NO: 4, 6 and 8.

Accordingly, claims 91-173 are pending in the instant application, of which claims 91-123, 126, 131-132, 138-169 are withdrawn from further consideration as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claim 125 is objected to because of the following informalities: Claim 125 recites non-elected, independent and distinct proteins which have been withdrawn from consideration. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 127-129 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant's newly submitted claims recite polypeptides comprising amino acids 31-55 or 51-86 or 110-140 of SEQ ID NO: 2. However Applicant has not pointed to support for claiming a polypeptide comprising only these specifically identified amino acids. Consequently, Applicant

is required to demonstrate clear support for the newly added material (Page and line number of specification) or cancel the newly added material.

4. Claims 124, 127-130, 133-137, and 170-173, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 124, 127-130, 133-137 and 170-173 recite an isolated polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to the complement of a DNA sequence encoding a Neisseria surface protein, wherein said Neisseria surface protein; is resistant to proteinase K and has an apparent molecular weight of 22 kDa, wherein said polypeptide is antigenic.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 2 alone is insufficient to describe the genus. Thus, Applicant's have not described a

function of the isolated polypeptide which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. Furthermore, the function of the specifically claimed fragments (e.g., amino acids 31-55 of SEQ ID NO: 2, etc.) is not set forth, the written description of the instant application is supportive of only an antigenic peptide consisting the fragment, since additional amino acids on the N-terminus or C-terminus will have a profound impact on the activity of the protein.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

5. Claims 133-137 and 170-173 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vaccine composition comprising the polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for pharmaceutical/vaccine compositions comprising a polypeptide which hybridizes under stringent conditions to a DNA sequence

encoding a Neisseria surface protein which is resistant to proteinase K and has an apparent molecular weight of 22 kDa. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification provides insufficient guidance of how to use the claimed polypeptides as a vaccine. It is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A *et al.*,(ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen."

A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

It is noted that Applicant's specification demonstrates protection in mice against Neisseria meningitidis strain 608B lethal challenge when vaccinated with the 22 kDa surface protein identified as SEQ ID NO: 2. (Page 52). However, this is the only working example. While those of skill in the art would recognize that the protein identified as SEQ ID NO: 2 is capable of

conferring protection to mice, these results are not commensurate in scope with Applicant's claim language encompassing all proteins capable of hybridizing under undefined conditions to a protein of undefined function. Since the art teaches of the unpredictability of using a single antigen for vaccination it would be an undue burden and be unpredictable to use the broadly claimed product for vaccination.

6. Claim 124 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "stringent conditions." Possibilities for hybridization are determined by the stringency of the procedure. Stringency, determined by the physical and chemical conditions, establishes the degree of hybridization. Without providing the chemical and physical conditions under which the hybridization is to be preformed as well as that of the wash step, one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 124, 133-137, 170 and 172 are rejected under 35 U.S.C. 102(a) as being anticipated by Merks *et al*.

The claims are directed to an isolated polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to the complement of a DNA sequence encoding a Neisseria surface protein, wherein said Neisseria surface protein is resistant to proteinase K, and has an apparent molecular weight of 22 kDa, wherein said polypeptide is antigenic.

Merks *et al* (WO 94/05703) disclose of a cell surface protein of Neisseria meningitidis with a molecular weight of about 20 kDa. Merks *et al* further disclose of the protein in combination with adjuvants and carriers as well as administration to an animal, and generating an antibody. (See abstract and pages 4-5).

In view that both the instantly filed application and the disclosure of Merks *et al* are surface proteins of Neisseria meningitidis with a molecular weight of about 20 kDa, the disclosure of Merks *et al* is deemed to anticipate the claimed invention.

It is noted that Merks *et al* do not characterize the protein as being resistant to proteinase K, however since the protein disclosed by Merks *et al* shares the same structural requirements as

set forth in the claims, as well as being isolated from the same source, with the same molecular weight, and same property of antigenicity, the feature of being resistant to proteinase K is deemed to be an inherent property.

Since the Patent office does not have the facilities for examining and comparing applicants' product with the product of the prior art reference, the burden is on applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

8. Claims 124, and 133-135, are rejected under 35 U.S.C. 102(b) as being anticipated by Bhattacharjee *et al.*

The claims are directed to an isolated polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to the complement of a DNA sequence encoding a Neisseria surface protein, wherein said Neisseria surface protein is resistant to proteinase K, and has an apparent molecular weight of 22 kDa, wherein said polypeptide is antigenic.

Bhattacharjee *et al* (Infection and Immunity Vol. 56, No. 4, pp 773-778, April 1988) disclose of a cell surface protein of Neisseria meningitidis with a molecular weight of about 22 kDa. (See abstract).

In view that both the instantly filed application and the disclosure of Bhattacharjee *et al* are surface proteins of Neisseria meningitidis with a molecular weight of about 22 kDa, the disclosure of Bhattacharjee *et al* is deemed to anticipate the claimed invention.

It is noted that Bhattacharjee *et al* do not characterize the protein as being resistant to proteinase K, however since the protein disclosed by Bhattacharjee *et al* shares the same structural requirements as set forth in the claims, as well as being isolated from the same source, with the same molecular weight, and same property of antigenicity, the feature of being resistant to proteinase K is deemed to be an inherent property.

Since the Patent office does not have the facilities for examining and comparing applicants' product with the product of the prior art reference, the burden is on applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 124-125, 127-130, 133-137, and 170-173 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,287,574. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims encompasses polypeptides comprising SEQ ID NO: 2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

December 26, 2002